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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,283	09/27/2000	John A. Giordano	22920.0003	6590
23767	7590	11/16/2004		
PRESTON GATES ELLIS & ROUVELAS MEEDS LLP 1735 NEW YORK AVENUE, NW, SUITE 500 WASHINGTON, DC 20006			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,283

Applicant(s)

GIORDANO ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 5, 2004 & September 7, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 155-170 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 163-170 is/are allowed.
- 6) ☒ Claim(s) 155-162 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted August 5, 2004 and September 7, 2004 is acknowledged.

Claim Rejections 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 155, 156, 158-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568).
3. Riley teaches an supplemental nutrient oral daily dosage composition comprising about 0.7 to about 15 mg Vitamin B1, about 0.7 to about 15 mg of vitamin B2, about 2 to 100 mg vitamin B6, about 6 to about 100 mg niacin, about 50 to about 800 mcg foliate (in the form of folic acid), about 4 to about 50 mg of pantothenic acid (in the for of d-calcium pantothenate), about 0.5 to about 40 mcg vitamin B12, about 5 to about 300 mcg biotin, about 5 to about 30 mg of zinc, about 10 to about 200 mcg selenium (in the form of L-selenomethionine), about 10 to about 300 mcg chromium, about 20 to about 1,000 mg vitamin C, about 5 to about 2,000 mg vitamin E. See, particularly, claim 1 and tables 2 and 3.
4. Riley does not teach expressly a composition consisting of the ingredients above.

However, it would have been prima facie obvious to one of ordinary skill in the art, at the time the claimed invention was made to make a composition consisting of the above nutritional components because each of the ingredients are known nutritional agents to human. It is prima

facie obvious to combine two or more agents each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of several known nutritional agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069.

5. Claim 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128), for reasons set forth above, and in further view of Anderson (US 5,278,329).

6. Riley and Wakat do not teach expressly the particular zinc salts herein. However, Anderson teaches that zinc L-methionine is a known chromium salt useful as zinc supplements. See particularly, the abstract, column 1, line 5 bridging column 2, line 20, and the claims. One of ordinary skill in the art would have been motivated to employ any known zinc salt (e.g., L-methionine) in the composition of Riley because a skilled artisan possessing a pharmaceutical active, also possesses the salts, acids and esters of the said active. Employing of a known salt, acid, and ester of a known compound in lieu of the compound itself is within the skill of the artisan. Moreover, the skilled artisan would expected the salts, acids esters of a known compound to exhibit therapeutical effects similar to those of the compounds itself.

Response to the Arguments

Applicants' amendments and remarks submitted August 5, 2004 have been fully considered, but are not persuasive with respect to the rejections set forth above. The arguments regarding to the rejections under 35 U.S.C. 112, first paragraph and rejections of claims 163-170 are persuasive.

As to the rejections of claims 155 to 162, the examiner maintains his position that each and every vitamins and minerals herein are well-known nutritional components. The combination of them would have been obvious. In re Kerkhoven, 205 USPQ 1069.

Reasons for allowance of claims 163-170

Claims 163 to 170 are directed to a nutritional composition comprising various vitamins and minerals with specific amounts of each and every ingredient. Even though the prior art teach the usefulness of the vitamins and minerals or mixture comprising the same, there is lack of sufficient guidance, direction or suggestion to reach the particular amounts of each and every ingredients herein claimed.

7. This application contains claims 53-116 drawn to an invention nonelected with traverse in Paper mailed February 21, 2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejoinder

8. The examiner had required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
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